



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,149	12/19/2001	Fatima Gebauer	71745-56434	1757

21874 7590 08/07/2003

EDWARDS & ANGELL, LLP
P.O. BOX 9169
BOSTON, MA 02209

EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
----------	--------------

1637

16

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,149

Applicant(s)

GEBAUER ET AL.

Examiner

Teresa E Strzelecka

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 13-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 8-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-12) in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 13-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made in Paper No. 9.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
4. Claims 13-15, which are improper multiple dependent claims, were not included in the restriction requirement. Applicants did not amend the claims, therefore they will not be rejoined with the elected claims 1-12.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on February 14, 2002 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Oath/Declaration

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Citizenship changes for Fatima Gebauer and Giovanna Bergamini are not initialed and not dated, and changes for Davide Corona are not dated.

Drawings

7. The drawings are objected to because:

A) Figure 11 does not contain a labeled Y-axis.

B) Figures 12A and 12 B seem to be showing results of similar experiments, i.e. time optimization of translation reaction. However, results for Cap and Cap-pA for the same time interval are contradictory: in Fig. 12A, at 60 minutes and 90 minutes, bars corresponding to Cap-pA are shorter than the ones corresponding to Cap alone, whereas the opposite is true in case of Figure 12B. There is no description in the specification of experiments which produced these results.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. No new matter should be introduced.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Before proceeding with the rejection it is noted that the part of claim 1 which refers to the amount of encoded protein produced is an intended result of the method step, not an active method step, therefore it will not be taken into account when the claimed invention is compared to the prior art.

10. Claims 1-4 rejected under 35 U.S.C. 102(b) as being anticipated by Iizuka et al. (Mol. Cell Biol., vol. 14, pp. 7322-7330, 1994; cited in the IDS).

Regarding claim 1, Iizuka et al. teach in vitro translation of a ribonucleic acid having both a 5' cap and a 3' poly A tail (capped and polyadenylated luciferase mRNA) by incubating a cell extract of a multicellular eukaryote with the ribonucleic acid under conditions such that translation of the RNA template to produce its encoded protein occurs (page 7324, paragraphs 7 and 8; Fig. 1; Fig. 3). The amount of encoded protein produced, in the wheat germ system, 6.8 (in relative units of luciferase activity), is greater than the total of the amount of the protein produced from RNA template which has a 5' cap but no poly A tail (2.2), and the amount of the protein produced from RNA template which has no 5' cap but has a poly A tail (2.5). In the rabbit reticulocyte system, the amount of the protein produced from RNA template which has a 5' cap but no poly A tail (2.6), and the amount of the protein produced from RNA template which has no 5' cap but has a poly A tail (1.5) add up to 4.1 units, which is within experimental error of the value of 3.7 units obtained for protein having both 5' cap and 3' poly A tail (Fig. 4).

Regarding claim 2, Iizuka et al. teach animal cell extract, rabbit reticulocyte cell extract (page 7324, paragraphs 7; Fig. 4).

Regarding claims 3 and 4, Iizuka et al. teach human cell extract, HeLa cell extract (page 7324, paragraphs 7; Fig. 4).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iizuka et al. (Mol. Cell Biol., vol. 14, pp. 7322-7330, 1994; cited in the IDS) and Scott et al. (Biochemistry, vol. 18, pp. 1588-1594, 1979).

A) Claim 5 is drawn to the method of claim 2 wherein the cell extract is an insect cell extract, claim 6 is drawn to the method of claim 5 wherein the cell extract is *Drosophila* cell extract, claim 7 is drawn to the method of claim 6 wherein the cell extract is *Drosophila* embryo cell extract.

B) Iizuka et al. do not teach insect cell extract, *Drosophila* cell extract or *Drosophila* embryo cell extract.

C) Scott et al. teach in vitro translation of proteins in cell extracts obtained from *Drosophila* cell culture and from *Drosophila* embryos (page 1589, paragraphs 5-12; Fig. 2; Fig. 5).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used *Drosophila* cell lysates and *Drosophila* embryo cell lysates of Scott et al. in the method of Iizuka et al. The motivation to do so, provided by Scott et al., would have been that *Drosophila* lysates synthesized high molecular weight proteins in greater abundance than other cell-free systems and the lysates were easy to prepare (page 1590, the last paragraph, continued on page 1591; page 1593, the last paragraph).

13. No references were found teaching or suggesting claims 8-12. Claims 8-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
August 5, 2003 TS


BJ FORMAN, PH.D.
PRIMARY EXAMINER